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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,428	05/10/2005	Jeffrey Keller Teumer	50393/004001	5032
21559	7590	03/05/2008		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER GOUGH, TIFFANY MAUREEN	
			ART UNIT 1657	PAPER NUMBER
			NOTIFICATION DATE 03/05/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/534,428	Applicant(s) TEUMER ET AL.	
	Examiner TIFFANY M. GOUGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-21 and 29-50 is/are pending in the application.
- 4a) Of the above claim(s) 34-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-21,29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/10/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2007 has been entered.

Claims 1, 7-21, 29-33 are pending and have been considered on the merits.
Claims 34-50 have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7-21,29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/01034 in view of WO 00/69449, WO 01/74164 and Kishimoto et al (Genes and Dev., 2000, p.1181-'85) supported by Zhu et al.

WO '034 discloses a method for producing new hair growth comprising culturing human dermal papilla cells in a conditioned medium. They show that co-cultivation allows rat papilla cells to retain their hair inducing capabilities through 56 passages (p.2, lines 7-10). WO'034 disclose that the human papilla cells cultured in a conditioned medium can expand rapidly for many passages in vitro while maintaining their hair inducing properties (p.2, lines 27-29). The cells used in the conditioned medium may be autologous or allogenic in source (p.4, lines 10-22). After culturing the papilla cells in the conditioned media, the papilla cells are then harvested and can be used directly or centrifuged, i.e. concentrated (p.5, lines 1-4).

Although, WO'034 does not specifically teach the number of passages of the dermal papilla cells, they do teach that the cells can expand for many passages and further teach the ability of rat cells under the same conditions to retain their hair inducing properties through 56 passages. Thus, it would be obvious to one of ordinary skill in the art at the time the invention was made to cultivate dermal papilla cells in a conditioned medium with cells of non-epidermal origin and expect success in maintaining the hair inducing properties through passages of more than seven.

WO '449 disclose conditioned cell culture medium compositions and their methods of use. The medium may be conditioned with any eukaryotic cell type (p.5, lines 30-34) including human hair papilla cells (p.45, lines 34), epithelial cells, stromal, parenchymal, mesenchymal cells, liver reserve cells, neural stem cells, pancreatic stem cells, fibroblasts including human dermal fibroblasts, endothelial cells, pericytes, macrophages, monocytes, plasma cells, mast cells, adipocytes, chondrocytes, keratinocytes (p.5, lines 32-35, p.8, lines 8-12, p.9 lines 31-35) from corresponding tissues including bone marrow, skin, liver, pancreas, kidney as well as genitourinary tract, i.e. encompassing the prostate (p. 12, lines 13-20). Cell lines may also be used in the conditioned medium but are carefully screened for human and animal pathogens, i.e. tested for risk factors associated with transplantation (see p. 14, lines 6-10). The medium may contain, but does not require the addition of additional growth factors and proteins, i.e. consisting essentially of the conditioned medium (p. 13, lines 8-12) and is serum-free (p. 11, lines 4-7). The medium may be in any form such as liquid, frozen, lyophilized, or dried (p.6, lines 18-20). The compositions are used to culture cells and further is formulated for methods of stimulating hair growth (p.7, lines 18-31). The conditioned medium is also concentrated by any methods known in the art (p.29, lines 1-9, p.46 lines 2-3).

Neither reference teaches cultivating hair inductive cells such as dermal papilla or sheath cells in conditioned medium conditioned with prostate epithelial cells. WO '164 teaches a method comprising culturing dermal papilla (DP) cells with cells expressing Wnt proteins to promote hair growth. The culturing of DP cells with Wnt maintains hair inductivity (p.1, lines

17-19). The Wnt expressing cells can be autologous or allogeneic to the DP cells (p.3, lines 11-17). The method comprises culturing DP cells to increase the number of DP cells, i.e. three or more passages (p.14, lines 1-2,26-28, p.23, lines 1-14) and then harvesting and returning the cells (p.14, lines 15-23).

Kishimoto et al (Genes and Dev., 2000, p.1181-'85) teach Wnt signaling effects on DP cells when the cells were exposed to cells expressing Wnts 3a,4,5a, 7a. They show that the hair inductive activity of DP cells is maintained in culture by Wnt signaling and that exogenous Wnt would extent hair cycle and promote hair growth (p.1184 col. 1).

Zhu et al demonstrate that prostate epithelial cells do express Wnt genes (abstract and Fig. 1A). Fig. 1A lane 1 clearly shows expression of most all genes in the Wnt gene family, including Wnt 4,5,7,11.

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to cultivate hair inductive cells such as dermal papilla (DP) cells in a conditioned medium as such methods are known in the art as taught by WO'034 and WO'449. Specifically it would have been obvious to condition the medium with prostate epithelial cells because as taught by WO'164 and Kishimoto, Wnt signaling and co-culturing DP cells with cells expressing Wnt clearly maintains and promotes hair growth and hair inductivity. While they do not teach prostate epithelial cells specifically, these cells are known to express Wnt, as is evidenced by Zhu who show expression of nearly all 19 Wnt genes. Thus, given what is known in the art of prostate epithelial cells Wnt expression and its ability to promote and maintain hair growth and inductivity, it

would have been obvious at the time of the invention to culture DP cells in a medium conditioned with prostate epithelial cells.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to culture DP cells in a medium conditioned with prostate epithelial cells with a reasonable expectation for successfully cultivating hair inductive cells because it is known in the art that Wnt levels positively regulate the ability of dermal papilla cells to promote hair growth and culturing DP cells with Wnt expressing cells maintains hair inductivity. Further, prostate epithelial cells are known to express Wnt genes such as those taught by WO-164.

Response to Arguments

Applicant's arguments with respect to claims 1,7-21,29-33 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tiffany M Gough/
Examiner, Art Unit 1657

/Ruth A. Davis/

Primary Examiner, Art Unit 1651